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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 2 1999

**WARNING LETTER**

**VIA FEDERAL EXPRESS**  
**VIA FACSIMILE**

Robert H. Gregg, II, D.D.S.  
President  
Millennium Dental Technologies, Incorporated  
10929 South Street, Suite 106B  
Cerritos, California 90703

Re: Periolase Nd: YAG Laser (a.k.a.  
Sunlase 800P Laser System), K983524

Dear Dr. Gregg:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Periolase Nd: YAG Laser (Periolase). This product is manufactured by Lares Research (Lares), distributed by Millennium Dental Technologies (Millennium), and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Periolase laser has been cleared under section 510(k) of the Act and is intended for incising, excising and coagulating intraoral soft tissue, including the marginal and interdental gingiva. This includes incising, excising, and coagulating the epithelium lining, the free or marginal gingiva, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

We have reviewed a June 10 press release published by Business Wire and issued jointly by Millennium and Lares Research which makes claims for Periolase that have not been cleared by the Agency. These uncleared claims include implications that the Periolase laser will eliminate or prevent bacterial infections, thereby reducing the risk of heart disease and decreasing the chances of damaging arteries and heart valves. The specific sentence we find objectionable is, "Moreover, with recent studies linking periodontal disease to an increase in heart attacks and strokes, laser vaporizing treatment is the most effective way to essentially eliminate the P. gingivalis bacteria found in hard to reach sub-gumline infections, significantly reducing the risk of heart disease and decreasing chances of having damaged arteries and heart valves."

We have also reviewed your web site at the internet address: <http://www.millenniumdental.com>. The web site contains claims that the Periolase laser can perform ENAP (excisional new

attachment procedure) and is capable of laser curettage. Your web site also mentions that Millennium offers comprehensive hands-on training in the laser ENAP technique. Our records indicate that the manufacturer was advised to delete all references to laser ENAP and to laser curettage from labeling and promotional materials. These claims, including any hands-on training, are also outside the scope of the cleared intended use of the device and constitute promotion of the device for off-label uses.

Marketing the Periolase for claims of laser curettage, ENAP, reducing or preventing bacterial infection, reducing the risk of heart disease and decreasing the damage to arteries and/or heart valves, causes your device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Periolase is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Periolase Laser. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

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A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office (HFR-PA20), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill". The signature is stylized with a large, sweeping "L" and a distinct "G".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health